

REMARKS

In the Office Action dated July 16, 2003, claim 1 was rejected under the judicially created doctrine of double patenting over claims 4 and 6 of U.S. Patent No. 6,564,798. The Examiner stated that the subject matter claimed in the present application is fully disclosed in the patent and is covered by the patent since the patent and the present application are claiming common subject matter, which the Examiner characterized as a computerized control unit, an expiratory valve, and an inspiratory section.

This rejection is respectfully traversed for the following reasons. First, the Examiner is certainly correct that a computerized control unit, an expiratory valve and an inspiratory section are disclosed and claimed in both the present application and the '798 patent, however, the same could be said of hundreds of other patents in the ventilator field, since those three components are fundamental to almost every ventilator. There is, however, no disclosure, and no claims, in '798 patent regarding recruitment, to which claim 1 of the present application is specifically directed, nor is there any description or claiming in the '798 patent of the specific manner of controlling the inspiratory unit and the expiratory valve as set forth in claim 1.

The '798 patent discloses and claims a specific manner of controlling an expiratory valve in a ventilator. Claims 4 and 6 of the '798 patent, which both depend from claim 1 of the '798 patent, describe the specific control, during a first interval, of an expiratory phase by opening the expiratory valve substantially fully, and measuring flow through the expiratory valve in the first interval or measuring pressure at the expiratory valve in this first interval, and determining if and when a predetermined condition is satisfied. Then a second interval of the expiratory phase

begins and during this second interval, the expiratory valve is regulated to produce an end pressure in the expiratory section of the ventilator. This has nothing whatsoever to do with recruitment, and is not related to any type of recruitment maneuver or procedure. The described control in claims 4 and 6 of the '798 patent, moreover, in no manner conforms to the steps set forth in claim 1 of the present application, regardless of whether the steps are for the purpose of recruiting a lung.

The Examiner stated there is no apparent reason why the Applicant was prevented from presenting claims corresponding to those of the present application during prosecution of the application which issued as '798 patent. In fact, there are several very good reasons. As noted above, the two disclosures, and the two sets of claims, have absolutely nothing to do with each other, since each is directed to solving a different problem. The '798 patent is directed to solving problems related to the control of an expiratory valve, and the present application relates to problems associated with conventional recruitment maneuvers. Moreover, the two applications have two different inventors. There is no reason why the inventor in the '798 patent would have any motivation to even think about recruitment maneuvers in the context of devising a method or an arrangement for controlling an expiratory valve. Of course, even in conventional techniques, recruitment may involve automated or manual control of an expiratory valve, however, this is a trivial and meaningless relationship between recruitment and controlling an expiratory valve, and simply because a patent discloses and claims a way of controlling an expiratory valve does not suggest any particular type of recruitment maneuver. Claim 1 of the present application, if allowed, therefore would not constitute double patenting over claims 4 and 6 of the '798 patent.

Claim 1 also was rejected under 35 U.S.C. §102(b) as being anticipated by Bird. This rejection also is traversed, for the following reasons.

Like the '798 patent, the Bird patent makes no mention whatsoever of recruitment, or efforts at solving problems associated with conventional recruitment techniques. This is most likely why, in the detailed substantiation of the rejection based on the Bird reference, the Examiner did not even mention the word "recruitment" even though that word is explicitly used in claim 1. In view of the fact that the Bird reference makes no mention whatsoever of recruitment, or recruitment techniques, it is not understood how the Examiner can contend that the Bird reference allegedly anticipates the subject matter of claim 1. Even if the Bird reference, for other purposes, and with no appreciation of recruitment, could be made to operate in the manner set forth in claim 1, this still would not constitute an anticipation of claim 1, because the Bird reference provides no teaching that any setting or motive operation of the ventilator disclosed therein has any benefit whatsoever for recruitment purposes.

Moreover, the described manner of operation for the different purpose described in the Bird reference does not correspond to the manner of operation set forth in claim 1 of the present application, even if the term "recruitment phase" is ignored. Claim 1 requires that breaths at an increased breathing rate be superimposed on the elevated pressure. As can be seen in Figures 2 and 3, this means that all of the breaths are, in accordance with the conventional meaning of "breaths" and "superimposed," are at a positive pressure above the elevated pressure. In other words, a positive pressure is generated in an inspiration phase to initiate the breath, and no action is taken during the expiration phase.

By contrast, the ventilator disclosed in the Bird reference is a conventional high frequency ventilator, wherein oscillations that are superimposed on the bias flow actively supply a small amount of gas and actively withdraw a small volume of gas. This is the typical manner of operation of all high frequency oscillation ventilators. This is described in the Bird reference at column 3, lines 4-9. This can also be seen in Figures 6, 8 and 9 of the Bird reference, which clearly show that the superimposed pulses oscillate around an average value, so that there are actually negative pressure portions wherein a volume of air is withdrawn.

By contrast, the device of claim 1 can not and is not intended to actively withdraw gas. The device of claim 1 operates as described above, wherein inspiration is actively assisted, but expiration is passive. This is also clear from the present specification in the paragraph bridging pages 3 and 4.

Claim 1, therefore, is not anticipated by the Bird reference.

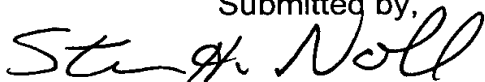
Claims 3 and 5-7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bird. This rejection is respectfully traversed for the same reasons as discussed above in connection with claim 1. Claims 3 and 5-7 embody the subject matter of claim 1 therein, and add further features to the novel and a non-obvious combination of claim 1. Claims 3 and 5-7, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Bird.

In the Office Action Summary, it was stated that claims 1-7 are rejected, however, there was no explicit substantiation for the rejection of claim 4 in the text of the Office Action. Applicant is therefore unable to respond to any rejection of claim 4.

Additionally, method claims 8-14 are submitted herewith, which track apparatus claims 1-7. These method claims are being submitted in view of the fact that the Examiner apparently gave no patentable weight to the term "recruitment phase" in claim 1. The Examiner may have felt justified in doing so on the basis that the Examiner believed the Bird reference disclosed components corresponding to the components of claim 1, and no patentable weight could be given to the purpose for which those components are operated. This is not the case with the method claims, wherein patentable weight must be given to the fact that the method claims are directed to a method for recruitment. Since none of the references of record disclose or suggest such a recruitment method, claims 8-14 are allowable as well.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,



(Reg. 28,982)

SCHIFF, HARDIN & WAITE

CUSTOMER NO. 26574

Patent Department

6600 Sears Tower

233 South Wacker Drive

Chicago, Illinois 60606

Telephone: 312/258-5790

Attorneys for Applicants.

CH1\ 4060316.1